specification as originally filed. No new matter was added by way of these amendments, and no new issues were raised. In particular, claim 41 had been amended to clarify the term "pluronic acid" as suggested by the Examiner. Claims 41, 44, 47, 48, 51 and 52 have been amended to clarify scope and place the claims in better form for consideration on appeal.

II. Status of the Claims

By the foregoing amendments, claims 41, 44, 47, 48, 51 and 52 have been amended. Upon entry of these amendments, claims 21-52 are pending in the present application.

III. Summary of the Office Action

In the Office Action mailed October 30, 2002, one requirement for restriction, one objection to the specification and six rejections of the claims have been made. Applicants respectfully offer the following remarks to overcome or traverse each of these elements of the Office Action, in light of the above amendments.

IV. Restriction Requirement

In the Office Action, at pages 2 and 3, it is asserted that the pending claims in the present application constitute independent or distinct inventions. The claims are allegedly drawn to the following inventions:

I. Claims 21-35 and 37-41, drawn to an injectable implant, classified in class 623, subclass 23.58; and

II. Claims 36 and 42-43, drawn to a freeze-dried product, classified in class 523, subclass 113.

In addition, it appears that the Examiner has also restricted out claims 44-52 as being directed to non-elected invention. Applicants hereby provisionally elect to prosecute the invention of Group I, represented by claims 21-35 and 37-41. The election is made without prejudice to or disclaimer of the other claims or inventions disclosed.

This election is made with traverse. The criteria for a proper requirement for restriction are that 1) the inventions must be independent or distinct as claimed; and 2) there must be a serious burden on the Examiner if restriction is not required. M.P.E.P. § 803.

Applicants respectfully assert that the claims in Groups I and II encompass subject matter

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that is closely related. All claims are drawn to compositions, methods, kits, vials or syringes using the compositions of claim 21. As such, a search of one group of claims is likely to encompass subject matter from the other group of claims. Moreover, even if, arguendo, it is assumed that the two groups represent distinct inventions, the second requirement set forth in M.P.E.P. § 803 has not been met, i.e., a serious burden if restriction were not required has not been shown. "If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions." M.P.E.P. § 803. Hence, reconsideration and withdrawal of the Restriction Requirement, and consideration and allowance of all pending claims, are respectfully requested.

V. The Rejection of Claims 21-35 and 37-41, Under 35 U.S.C. § 112, First Paragraph, is Traversed

Claims 21-35 and 37-41

In the Office Action, at page 4, claims 21-35 and 37-41 have been rejected for allegedly lacking an adequate written description. It is asserted that the language "materials of non-animal origin" lacks support in the specification, and was not originally contemplated by the inventors.

In the original application, at pages 1 and 2, Applicants outline examples of previous attempts to produce implants for subcutaneous or intradermal injection. In this description Applicants specifically refer to numerous problems associated with each of these previous attempts, including toxicity, non-biodegradability, rapid bioresorption, allergic reactions, and animal origin of the material(s) used for the implant (see, for example, page 1, lines 29-31; page 1, line 39, through page 2, line 1; and page 2, lines 17-19). Immediately following this section Applicants state that, "[t]he aim of the invention is to overcome the disadvantages of known products." Moreover, at page 5, lines 14-16, Applicants specifically cite the absence of any products of animal origin as a benefit, due to the decreased allergenicity of non-animal materials. The written description requirement of 35 U.S.C. § 112, first paragraph, is met "[i]f a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly

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described in the specification...." In re Alton, 37 U.S.P.Q.2d 1578, 1584 (Fed. Cir. 1996). Accordingly, Applicants assert that there is ample disclosure in the specification so that one of ordinary skill in the art would recognize that Applicants "had possession of the concept of what is claimed" at the time of filing. Ex parte Parks, 30 U.S.P.Q.2d 1234, 1236 (Bd. Pat. App. Int. 1994).

Claim 41

It is further asserted that the phrase "pluronic acid" is not adequately defined and may be a tradename. By the foregoing amendments Applicants have incorporated the Examiner's suggestion by inserting the phrase, "polyoxyethylene-polyoxypropylene block copolymer." As such, this portion of the rejection under 35 U.S.C. § 112, first paragraph, has been rendered moot.

In view of the foregoing remarks, Applicants respectfully submit that the present specification fully describes the invention as claimed. Reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, are therefore respectfully requested.

VI. The Rejection of Claims 21-35 and 37-41 Under 35 U.S.C. § 112, Second Paragraph, is Traversed

In the Office Action, at pages 4 and 5, claims 21-35 and 37-41 have been rejected, under 35 U.S.C. § 112, second paragraph, for use of the phrase, "non-animal origin." Applicants submit that the claims satisfy all requirements of 35 U.S.C. § 112, second paragraph.

Claims 21-35 and 37-41

It is asserted that "non-animal origin" lacks antecedent basis in the specification, and its meaning is indefinite. As discussed above, the support for the phrase "non-animal origin" can be found in the specification at pages 1 and 2, and on page 5, at lines 14-16. For example, at page 5, lines 14-16, Applicants have described the present invention as "not contain[ing] any product of animal origin." The disclosure fully, and unquestionably establishes antecedent basis for the phrase "non-animal origin."

There is no requirement that the words in the claim must match those used in the

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specification disclosure. Applicants are given a great deal of latitude in how they choose to define their invention so long as the terms and phrases used define the invention with a reasonable degree of clarity and precision. M.P.E.P. § 2173.05(e).

It is also asserted that "it is not clear what constitutes a material of animal origin and what does not." In the specification at pages 1 and 2, Applicants have given examples of problems associated with materials of animal origin (e.g., toxicity, allergenicity, etc.), which demonstrate the properties of materials of animal origin that are to be avoided as encompassed by the claims. As such, one of ordinary skill in the art, by referring only to the specification, will be able to determine what is meant by the phrase "non-animal material."

Claim 41

Finally, it is argued that the phrase "pluronic acid" renders claim 41 indefinite because "pluronic acid" is a tradename and not the actual material described. By the foregoing amendments Applicants have incorporated the Examiner's suggestion by inserting the phrase, "polyoxyethylene-polyoxypropylene block copolymer." As such, this portion of the rejection under 35 U.S.C. § 112, second paragraph, has been rendered moot.

In view of the foregoing remarks, claims 21-35 and 37-41 comply with the requirements of 35 U.S.C. § 112, second paragraph. Reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, are therefore respectfully requested.

VII. The Objection to the Specification

In the Office Action, at page 5, the specification is objected to for allegedly failing to define what is meant by "apyrogenic mannitol." Apyrogenic is defined as "not producing fever." Dorland's Illustrated Medical Dictionary 117 (27th ed. 1988) (copy attached). Apyrogenic mannitol, therefore, is not chemically distinct from mannitol, but the term apyrogenic merely refers to the fact that the mannitol has been sterilized and will not produce a fever. One of ordinary skill in the art of pharmaceutical chemistry would recognize the meaning of this term. Reconsideration and withdrawal of this objection is respectfully requested.

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VIII. The Rejection of Claims 21, 24, 27-31, 34, 35, and 37-40 Under 35 U.S.C. § 102(e), is Traversed.

In the Office Action, at pages 5-7, claims 21, 24, 27-31, 34, 35, and 37-40 have been rejected, under 35 U.S.C. § 102(e), as allegedly being anticipated by Ron et al. (U.S. Pat. No. 5,597,897). Ron et al. fails to anticipate the present invention.

The Examiner presents two arguments, 1) since Ron et al. use carboxymethylcellulose (CMC) in the same concentration as Applicant, the physical properties of Ron et al.'s implant must be the same as that of the claimed invention; and 2) since the osteogenic protein of Ron et al. can allegedly be made by chemical synthesis, the composition taught in this reference may contain only materials of non-animal origin, as recited in the present claims. The arguments raised in the Office Action are not tenable.

Claim 21 of the present invention relates to a bioresorbable injectable implant for human administration consisting essentially of bioresorbable microspheres or microparticles in a gel consisting essentially of materials of non-human origin, said microspheres or microparticles consisting of at least one polymer of non-animal origin selected from the group consisting of lactic acid polymers, glycolic acid polymers, and lactic acid-glycolic acid polymers.

Ron et al. fails to even remotely suggest a gel, much less an injectable gel. A gel is defined as "a colloid in which the disperse phase has combined with the continuous phase to produce a jelly-like product." Hawley's Condensed Chemical Dictionary 555 (12th Ed. 1993). The specification of Ron et al. teaches that their implant is "a malleable (putty-like) composite...that handles appropriately for surgical implantation into an injury site." (column 4, line 66- column5, line 1). One of ordinary skill in the art understands the definition of "gel," and would never consider a "putty-like" composition to fall within that definition. Moreover, the composition of Ron et al. would obviously not be suitable for injection into a patient as recited in the claimed invention.

In the Office Action it is assumed that since Ron et al. allegedly utilizes a similar concentration of CMC in their "putty-like" implant, that the physical characteristics of that composition MUST be similar to the claimed composition. This is wrong as a matter of science and as a matter of law. In addition to CMC, Ron et al.'s implant composition contains protein and large, porous particles, neither of which is present in the claimed invention. It is incorrect to

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assume that two different multi-component compositions will have the same physical properties simply because of a single common element. Moreover, the CMC is utilized in Ron et al.'s composition as a sequestering agent, and not as a gelling agent as in the claimed invention. The fact that the use of a gelling agent has not even been considered by Ron et al. is emphasized by the fact that many of the disclosed sequestering agents are not considered to be suitable gelling agents.

Also, Ron et al. state that only lower viscosity formulations, i.e., solutions, are suitable for injection (see column 5, lines 50-52 and column 6, lines 5-7). Therefore the addition of a gelling agent would be contrary to the teachings of Ron et al.

The Office action essentially argues that the physical properties of the entire composition, composed of multiple elements, are inherent features of a single component of that composition and not influenced by any of the other components. Further, it is argued that Ron et al. may have considered sequestering agents as gelling agents since one of the many sequestering agents is utilized by the claimed invention as a gelling agent. Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. Continental Can Co. U.S.A., Inc. v. Monsanto Co., 948 F.2d 1264, 1269 (Fed. Cir. 1991) (emphasis added). Inherency requires that the recited results or structure must necessarily be obtained, not merely that it might be achieved. See Electra Medical Systems S.A. v. Cooper Life Sciences, Inc., 32 U.S.P.Q.2d 1017 (Fed. Cir. 1994); In re Oelrich, 212 U.S.P.Q. 323 (C.C.P.A. 1981) and In re Rebertson, 49 U.S.P.Q.2d 1949 (Fed. Cir. 1999). Applicants suggest that the physical properties (i.e., gelatinous nature) of multi-component compositions are defined by the properties of all components and not one single component. Moreover, the physical properties of a given composition in the presence of one set of compounds will not necessarily be the same in the presence of a second set of compounds.

Even if, arguendo, Ron et al.'s disclosure could be considered to suggest the claimed invention, which is not the case, it would not be considered enabled. To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter. PPG Industries, Inc. v. Guardian Industries Corp., 75 F.3d 1558, 1566 (Fed. Cir. 1996). Ron et al. do not teach how to generate the injectable gel of the claimed invention.

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In the Office Action it is stated that the composition of Ron et al. may contain only materials of non-animal origin because the entire sequence of the osteogenic proteins can be synthesized chemically. This is incorrect. Nothing in Ron et al. suggests that the osteogenic protein required could be synthesized chemically. The mere chance that something might occur is not sufficient for anticipation due to inherency. In re Oelrich, 212 U.S.P.Q. 323 (C.C.P.A. 1981) and In re Rebertson, 49 U.S.P.Q.2d 1949 (Fed. Cir. 1999). Furthermore, as of the filing date of the present application, chemical synthesis of peptides and proteins was limited to oligopeptides of less than 100, and most commonly less than 50 residues. U.S. Pat No. 4,816,513. The three osteogenic proteins disclosed by Ron et al. are BMP-1, BMP-2 and BMP-8, which contain 986, 402 and 114 amino acids respectively (see Genbank report P13497, Genbank report P34820 and US Patent 5,013,649); therefore, the protein component of Ron et al's composition could not have been synthesized chemically and could not consist essentially of materials of non-human origin. However, even if Ron et al. were able to chemically generate a synthetic protein that contained the entire sequence, it would still include all of the properties of its "natural" counterpart, and as such, would suffer from the problems of toxicity and allergenicity.

Under 35 U.S.C. § 102, a claim can only be anticipated if every element in the claim is expressly or inherently disclosed in a single prior art reference. See Kalman v. Kimberly Clark Corp., 713 F.2d 760, 771 (Fed. Cir. 1983), cert. denied, 465 U.S. 1026 (1984). Since Ron et al. does not expressly or inherently disclose either an injectable gel, or consist essentially of materials of non-animal origin, this reference cannot and does not anticipate the claims in their current form.

Claim 24

It is further asserted that the range of "about 150-850 microns" recited by Ron et al. falls within the claimed range of 5 to less than 150. Applicants respectfully disagree. However, claim 24 depends from claim 21. As stated above, Ron et al. does not disclose all the elements of claim 21, and therefore can not anticipate claim 24, which depends therefrom.

Claim 30 and 31

In the Office Action it is argued that, although there is no specific recitation of specific

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viscosity in the disclosure of Ron et al., because the molecular weight of the polymer used by Ron et al. is allegedly similar to that used in the claimed invention, the viscosity MUST be the same. Applicants respectfully disagree. However, claims 30 and 31 both depend from claim 21. As stated above, Ron et al. does not disclose all the elements of claim 21, and therefore can not anticipate claims 30 and 31, which depend therefrom.

Claim 36

In the Office Action it is further argued that example 4 of Ron et al. anticipates claim 36 of the present invention for reasons that are not explicitly stated. Applicants respectfully disagree with this assertion. However, claim 36 depends from claim 21. As stated above, Ron et al. does not disclose all the elements of claim 21, and therefore can not anticipate claim 36, which depends therefrom.

Claims 36-40

Finally, it is asserted that claims 36-40 are anticipated by Ron et al., because Ron et al. allegedly disclose the use of appropriate surfactants in their implant composition. Applicants respectfully disagree with this assertion. However, claims 36-40 depend from claims 21 and 37. As stated above, Ron et al. does not disclose all the elements of claims 21 or 37, and therefore can not anticipate claims 36-40, which depend there from.

For the reasons stated above, Applicants submit that Ron et al., does not disclose all elements of the claimed invention. As such, the rejection of claims 21, 24, 27-31, 34, 35, and 37-40, under 35 U.S.C. § 102(e), is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

IX. The Rejection of Claims 26, 32 and 33under35 U.S.C. § 103(a), is Traversed.

In the Office Action at pages 7 and 8, claims 25, 32 and 33 have been rejected, under 35 U.S.C. § 103(a) as allegedly being unpatentable over Ron et al. (U.S. Patent No. 5,597,897). Ron et al. fails to render obvious claims 26, 32 and 33.

Claim 26

It is argued that claim 26 is obvious over Ron et al. because biodegradation time is allegedly a function of molecular weight, hence, it would have been obvious for one of ordinary skill in the art to alter biodegradation time in order to allow for natural tissue replacement in different parts of the body. Applicants respectfully disagree.

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In rejecting a claim under 35 U.S.C. § 103(a) a prima facie case of obviousness must be established. In order to do so the following burdens must be satisfied. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine referenced teachings to obtain the claimed invention. See In re Fine, 5 USPQ2d 1596,1598 (Fed. Cir. 1988). Second, there must be a reasonable expectation of success. See In re Dow Chem. Co., 837 F.2d 469, 473 (Fed. Cir. 1988). And finally, the prior art references must teach or suggest all the claim limitations. In the present case, none of the burdens have been satisfied. Nowhere in the disclosure of Ron et al. do the inventors suggest or contemplate the modification of their compositions and methods for the purpose of allowing for natural tissue regeneration in areas other than osteogenic regeneration. Even if such a suggestion were present, there would be no reasonable expectation of success in producing the claimed compositions due to the differences between the compositions of Ron et al.and the claimed invention. More specifically, Ron et al. does not teach all the claim elements of claim 21, from which claim 26 depends. For example, Ron et al. does not expressly or inherently disclose either the presence of an injectable gel composition, nor does the disclosed composition consist essentially of materials of non-animal origin the claimed invention. No references have been cited that cure the deficiencies of Ron et al., and as such, this reference does not establish a prima facie case of obviousness over claim 26 of the present application.

Claim 32 and 33

It is further argued that claims 32 and 33 are rendered obvious by Ron et al. due to the inherent properties present in Ron et al.'s composition. As mentioned above, in order to establish a case of obviousness under 35 U.S.C. § 103(a), the cited reference(s) much contain all of the claim elements. As mentioned previously, Ron et al. does not teach all the claim elements of claim 21, from which claims 32 and 33 depend. For example, Ron et al. does not expressly or inherently disclose either the presence of an injectable composition, nor does the disclosed composition consist essentially of materials of non-animal origin. No references have been cited that cure the deficiencies of Ron et al., and as such, this reference does not establish a prima facie case of obviousness over claims 32 and 33 of the present application.

Reconsideration and withdrawal of this rejection of claims 21, 24, 27-31, 34, 35, and 37-40, under 35 U.S.C. § 103(a) are respectfully requested.

The Rejection of Claims 21-25 and 30-31 Under 35 U.S.C. § 103(a) is Traversed.

In the Office Action at page 8, claims 21-25 and 30-31 have been rejected under 35 U.S.C. § 103(a), as being obvious over Scopelianos et al. (EP 0711794) in light of Orly et al. (WO 93/13755). (As discussed during the interview, apparently, the examiner intended to rely upon EP 0711 548 to Scopelianos et al.) These cited references fail to render obvious claims 21-25 and 30-31.

As appreciated by the Examiner, Scopelianos et al. fails to suggest a gelation material. This deficiency is allegedly cured by Orly et al.

In order to establish a prima facie case of obviousness under 35 U.S.C. § 103(a), it must be shown that all claim elements are present in the cited references, and moreover, a motivation to combine those references and a reasonable expectation of success once the references are combined must be established. See In re Fine, 5 USPQ2d 1596,1598 (Fed. Cir. 1988). See In re Dow Chem. Co., 837 F.2d 469, 473 (Fed. Cir. 1988). In the present case this has not been done. Scopelianos suggests a injectable microdispersion made of ε-caprolactone polymers and not polylactic or polyglycolic polymers as recited by the claimed invention. The terms "polylactic" and "polyglycolic" polymers refer to homopolymers and do not encompass co-polymers as are recited in Scopelianos. Moreover, Scopelianos teaches away from the use of polylactic polymers in column 2, lines 10-25, where he states:

Soft tissue repair or augmentation has also been proposed using lactic acid based polymer blends of amorphous oligomers with crystalline oligomers or polymers.... However, these blends do not appear to be suitable for use as injectable soft tissue defect fillers, because they are too viscous to be injected through a needle which significantly limits the utility of these blends.

Scopelianos further teaches away from a gel since the injectable composition according to Scopelianos must be low viscosity. Accordingly, to add a gelling agent would be contrary to the teachings of Scopelianos et al. Orly does not cure these deficiencies. The "viscous biocompatible carrier solution" suggested by Orly et al. consists of collagen and

glycosaminoglycan compositions, both of which are of animal origin. Therefore, the combination of Scopelianos and Orly does not teach all the elements of the claimed invention.

Further, Scopelianos does not suggest the use of animal-based viscous biocompatible carrier solutions, and there would be no motivation to combine the two teachings. Moreover, utilizing the combined teachings of Scopelianos, which teaches away from the use of lactic acid polymers and utilizes ε-caprolactone for injectable microdispersions, with Orly et al., which teaches the use of animal-based viscous biocompatible carrier solutions, would not result in a reasonable expectation of success in generating the bioresorbable injectable implant of the claimed invention.

As such, a prima facie case of obviousness has not been established. Reconsideration and withdrawal of the rejection of claims 21-25 and 30-31 under 35 U.S.C. § 103(a) over Scopelianos et al. and Orly et al. are respectfully requested.

XI. The Rejection of Claim 41 Under 35 U.S.C. § 103(a) is Traversed.

In the Office Action, at page 8, claim 41 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Ron et al. in view of Sander et al. (U.S. 5,356,629).

The Office Action states that Ron et al. teaches all the limitations of claim 41, and implicitly claim 37, from which claim 41 depends, except for the use of surfactant, which is allegedly cured by Sander et al.

As discussed above, at a minimum, Ron et al. fails to disclose the presence of an injectable implant that consists essentially of materials of non-animal origin as recited by the claimed invention. Sander et al. teaches the use of surfactants in moldable implants, which are not capable of being injected. Therefore, the combination of Ron et al. and Sander et al. does not contain all the elements of the claimed invention. Even if, arguendo, Sander et al. did teach the use of the claimed surfactant in the injectable implants of the invention, it would not cure the defects of Ron et al.

The combination of Ron et al. and Sander et al. does not contain all the elements of the claimed invention, and as such, does not render the claimed invention obvious. Reconsideration and withdrawal of this rejection of claim 41 under 35 U.S.C. § 103(a) over Ron et al. and Sander et al. are respectfully requested.

X. **Summary**

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn.

Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided. Prompt and favorable consideration of this amendment and reply are respectfully requested.

Respectfully submitted,

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Copy of Amended Claims Showing Changes Made

41. (Once amended) The bioresorbable injectable implant according to claim 37, wherein said surfactant is at least one member selected from the group consisting of polyoxyethylene sorbitan monooleate and [pluronic acid] polyoxyethylene-polyoxypropylene block copolymer surfactant.

44. (Once amended) A method of making a bioresorbable injectable implant free of materials of animal origin [comprising] consisting essentially of the steps of:

a) providing polymer microspheres or microparticles [comprising] consisting essentially of[:] at least one polymer selected from the group consisting of lactic acid polymers, glycolic acid polymers, and lactic acid-glycolic acid co-polymers[, and mixtures thereof];

b)providing a gel capable of suspending said microspheres or microparticles, wherein said gel [comprises] consists essentially of:

water for injection;

from about 0.1 to about 7.5% (wt/wt) of an injectable gelling agent; and

a surfactant,

c)dispersing said microspheres or microparticles in said gel at a proportion of from about 50 to about 300 grams of microspheres or microparticles per liter of gel;

d) packaging said dispersion into sterilizable, sealable containers; and

e)sterilizing said container.

47. (Once amended) A syringe containing a unit dosage form of a bioresorbable injectable implant free of material of animal origin suitable for administration to a human patient in need thereof said implant [comprising] consisting essentially of:

polymer microspheres or microparticles [comprising] consisting of[:] at least one polymer selected from the group consisting of lactic acid polymers, glycolic acid polymers, and lactic acid-glycolic acid co-polymers[, and mixtures thereof]; and

a pharmaceutically acceptable gel capable of suspending said microspheres or microparticles, wherein said gel [comprises] consists essentially of:

water for injection;

from about 0.1 to about 7.5% (wt/wt) of an injectable gelling agent; and

a surfactant.

48. (Once amended) A vial containing a unit dosage for of a bioresorbable injectable implant free of materials of animal origin suitable for administration to a human patient in need thereof said implant [comprising] consisting essentially of:

polymer microspheres or microparticles [comprising] consisting of[;] at least one polymer selected from the group consisting of lactic acid polymers, glycolic acid polymers, and lactic acid-glycolic acid co-polymers[, and mixtures thereof]; and

a pharmaceutically acceptable gel capable of suspending said microspheres or microparticles, wherein said gel [comprises] consists essentially of:

water for injection;

from about 0.1 to about 7.5% (wt/wt) of an injectable gelling agent; and

a surfactant.

50. (Once Amended) A method of making a freeze-dried material for reconstitution as a bioresorbable injectable implant free of material of animal origin suitable for administration to a human patient in need thereof [comprising] consisting essentially of the steps of:

microparticles or microspheres [comprising] consisting of :

at least one polymer selected from the group consisting of lactic acid polymers, glycolic acid polymers, lactic acid-glycolic acid co-polymers, and mixtures thereof;

providing a freeze-drying medium comprising:

a gelling agent free of materials of animal origin,

a cryoprotecting agent,

a surfactant, and

water for injection;

sterilizing said medium;

mixing about 100mg of said microparticles or microspheres with about 1.0 gram of said freeze-drying medium;

homogeneously dispersing said mixture; and

freeze-drying said dispersion.

51. (Once amended) A kit comprising:

a vial containing an amount of freeze-dried material which upon addition of water for injection is capable of reconstituting a unit dosage of a bioresorbable injectable implant, free of materials of animal origin, suitable for administration to a human patient in need thereof, said freeze-dried material consists essentially of:

microspheres or microparticles consisting of at least one polymer selected from the group consisting of lactic acid polymers, glycolic acid polymers, and lactic acid-glycolic acid co-polymers; and

a composition that forms a gel when mixed with water consisting essentially of:

a cryoprotecting agent;

a gelling agent; and

a surfactant;

and an ampule containing a unit dosage of said water for injection.

52 (once amended) A kit [comprising] consisting essentially of :

a two-compartment syringe wherein:

a first compartment contains an amount of freeze dried material, which upon addition of water for injection is capable of reconstituting a unit dosage of a bioresorbable implant, free of materials of animal origin, suitable for administration to a human patient in need thereof, said freeze-dried material consisting essentially of:

microspheres or microparticles consisting of at least one polymer selected from the group consisting of lactic acid polymers, glycolic acid polymers, and lactic acid-glycolic acid co-polymers; and

a composition that forms a gel when mixed with water consisting essentially of:

a cryoprotecting agent;

a gelling agent; and

a surfactant;

wherein a second compartment contains a unit dosage of said water for injection.